Baxter

# 510(K) SUMMARY

K 010566

**Submitted by:**

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I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

**Name/Classification of Device**

Infusion Pump/ Class II, 80FRN – 21 CFR 880.5725

**Trade Names:**

Colleague Volumetric Infusion Pumps

**Predicate Devices:**

AS50 Syringe Infusion Pump
Colleague Volumetric Infusion Pumps

**Statement of Intended Use:**

Colleague Volumetric Infusion Pumps are electronic infusion pumps indicated for continuous or intermittent delivery of solutions through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural or irrigation of fluid spaces.

**Device Description:**

Colleague pumps use a shuttle and valve control system mechanism to provide accurate, continuous infusions. Colleague provides continuous infusion and combined modes of operation. The pumps have configurable input parameters, which allow institutions to pre-select which modes of operation will be available to users and which units of measure will be used for data entry. Baxter Healthcare proposes to modify the Colleague family of infusion pumps with the addition of a new, configurable software feature.

**Summary of Technological Characteristics of New Device to Predicate Devices**

The technological features of the modified Colleague Volumetric Infusion Pumps do not differ from the currently marketed Colleague Volumetric Infusion Pumps. The subject and predicate Colleague devices are similar in design, material composition, components, labeling, and manufacturing processes. The subject and predicate Colleague devices are identical in intended use. The proposed software feature is similar to that found in AS50 infusion pumps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2001

Ms. Jennifer M. Paine
Regulatory Affairs Associate
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073

Re: K010566
Trade/Device Name: Colleague Volumetric Infusion Pump
Regulation Number: 880.5725
Regulatory Class: II
Product Code: FRN
Dated: February 23, 2001
Received: February 26, 2001

Dear Ms. Paine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K010566

**Device Name:** Colleague Volumetric Infusion Pumps

**Indications for Use:**

The Baxter Colleague Volumetric Infusion Pumps are designed to meet the fluid delivery needs of today's evolving health care environment. These pumps can be utilized for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural or irrigation of fluid spaces applications.

Fluid delivery applications include:

- parenteral fluids, drugs and electrolytes (e.g. cardiovascular drugs, antibiotics, anesthetics, analgesics, chemotherapy agents, total parenteral nutrition products, lipids, solutions for irrigation procedures, etc.); and
- whole blood and blood products.

Colleague Volumetric Infusion Pumps are designed to travel the continuum of care, following the patient into a variety of care areas, including, but not limited to:

- Hospital:
  - General Floor
  - Medical/Surgical
  - Critical/Intensive Care Areas
  - Pediatrics/Neonatal
  - Labor/Delivery/Post Partum
  - OR/Anesthesia
  - Post Anesthesia/Recovery
  - Cardiac Cath Lab
  - Emergency Room
  - Burn/Trauma Units
  - Oncology
- Mobile Intensive Care
- Nursing Homes
- Homecare*
- Blood Centers
- Nuclear Medicine
- Hospice
- Subacute Facilities
- Outpatient/Surgical Centers
- Long Term Care

*Colleague and Colleague CX pumps only.

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-the-Counter Use** _____
**(Per 21 CFR 801.109)**

(Optional Format 1-2-96)

Rebecca Cocente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010566